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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/235,986	01/22/1999	WAYNE A. HENDRICKSON	58323/JPW/PT	2152

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/235,986	Applicant(s) HENDRICKSON ET AL.	
	Examiner Marianne P. Allen	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Applicant's arguments filed 7/28/04 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 are under consideration by the examiner.

Claim Rejections - 35 USC § 112

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

This rejection is maintained for reasons of record. Claims 1-12 are original claims; however, they have been substantively amended several times. Applicant has pointed to basis in the appendix (pages A-1 through A-7) to the response.

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Comparison of independent claims 1 and 7 alone to the basis pointed to in applicant's chart reveals that basis for the system of claim 1 is premised on Figure 1 and pages 12-16 and 20-21 of the specification and that basis for the process of claim 1 is premised on pages 10-16 and 20-22 of the specification. The system components and method steps set forth here neither match those of the claims in a broad sense or in particulars.

For example, Figure 1 has all of the components linked to a central control apparatus and genomics database which is not a limitation of the claims. The control apparatus and database are one unit. Components 6, 7, and 8 are also linked which is not a limitation of the claims.

A fair reading of the specification as originally filed would not convey to one of ordinary skill in the art that what is now claimed was the contemplated invention. Applicant may not recast or repackage the method steps originally contemplated into different combinations after the fact. The presently claimed methods as written are conceptually different from those claims originally filed and the methods disclosed in the specification as filed. They constitute new matter.

Claim Rejections - 35 USC § 112

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some aspects of the claimed method and system, does not reasonably provide enablement for the breadth of what is encompassed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-6 are directed to a system comprising a database, at least one bioinformatics tool, a protein synthesis means having a screening means, a protein processing means, a

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crystallization means, an X-ray crystallography means, a structure extraction means, and a homology model building tool.

As set forth in the prior Office actions, these systems claims do not make clear whether the claimed system is an integrated, turn-key system or fully automated system or whether it embraces discrete components that are not physically, structurally, or functionally related. For example, the claims recite no limitations with respect to how the screening means is interrelated or associated with the structure extraction means, if at all. However, the term “system” does appear to imply some interrelationship. Interpreting the claim using an English language definition, Webster’s defines a “system” as “a regularly interacting or interdependent group of items forming a unified whole.”

As set forth in the prior Office action, claims 1-6 are considered to encompass an integrated (in some unidentified fashion), turn-key system and/or fully automated system that is not enabled. Applicant is reminded that an adequate disclosure of a device requires details of how complex components are constructed and perform the desired function, particularly if the specification does not detail how the parts should be interconnected and controlled. Block diagrams with functional labels do not indicate whether the parts are “off the shelf” or must be specifically constructed or modified for applicant’s system. See MPEP 2164.06(a).

Applicant’s arguments regarding beamtime being readily leased by general users (set forth on page 14 of the response) are persuasive. However, there is no argument nor evidence of record that such synchrotron facilities would permit physical, structural, or functional connection with any or all of the devices set forth in the claims.

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Applicant is requested to explicitly set forth on the record what they believe the claimed system is directed to with respect to integration of components or lack thereof.

With respect to claims 7-12, the claimed method fails to particularly point out what steps are to be performed and how they are to be performed. This portion of the rejection is maintained for reasons of record. Applicant has argued 35 USC 112, sixth paragraph. The claims have not been treated under 35 USC 112, sixth paragraph. Applicant must show why the claim language invokes 35 USC 112, sixth paragraph, with respect to these claims. Applicant is requested to point to the particular means specified in the written description and equivalents thereof to perform the particular function. It does not appear that the corresponding structure, material, or acts are set forth in the written description necessary to perform the function.

Applicant cites *S3 Inc. v. nVIDIA*, 59 USPQ 2d 1745 (CAFC 2001). This decision is not germane to enablement as it addresses indefiniteness under 35 USC 112, 2nd paragraph. In the instant application, the specification is no more illuminating than the claims with regard to the positive, active steps to perform.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 recite "homologous sequences." However, it is unclear what level of homology is required to meet the limitation of the claims.

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Claims 1 and 7 recite “a plurality of target proteins which are members of the family.” However, the criteria that define a family are not provided. It is unclear how a target is selected (what parameters or criteria are used) and how many targets are selected.

Applicant argues that various known programs can be used and that one of ordinary skill in the art would not find these two phrases unambiguous. This is unpersuasive. The claims and specification must particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has not provided an art understood meaning for these phrases either within the specification or using art recognized documentation.

Claims 1 and 7 have been amended to recite “which are effective as the target proteins.” It is not known what is meant by this phrase. What defines an effective target protein?

Claims 1 and 7 have been amended to recite “screening products of the synthesis to choose selected synthesized products for processing.” However, the criteria or parameters for the selection are not provided.

With respect to claims 1-6, the claimed system does not set forth the relationship of the database, bioinformatics tool, protein synthesis means, protein processing means, crystallization means, X-ray crystallography means, and so forth. That is, the claim language does not reflect an integrated or turn-key system where the components are related or linked to each other in some fashion. As written, the claim appears to be directed to a collection of laboratory equipment or machines. A collection of laboratory equipment or machines does not define a system. See art rejection and discussion below and enablement rejection above.

With respect to claims 7-12, the method steps as written are internally inconsistent and unclear. For example, in step (a) the database has sequence information for a first plurality of

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proteins and structural information and functional information for a second plurality of proteins. (Note that it is unclear if this is a partitioned database for the first and second plurality as they do not contain the same types of information.) In step (g), the refined model is stored in the database. Note that part (a) does not require that the structural information include a refined model or a homology model. In step (j), the database is updated to link the refined model to other databases. Note that part (a) does not require that the database have links to any information at all.

Claim Rejections - 35 USC § 102

Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated because the invention was known by others in this country before the invention thereof by applicant for a patent as evidenced by the Workshop on Structural Genomics held at Argonne National Laboratories held January 1998, National Institute of General Medical Sciences (NIGMS) Protein Structure Initiative (PSI) held 4/24/98, NIGMS Genomics Project Planning Meeting held 11/24/98, Structural Genomics Meeting held October 1998 in Avalon, New Jersey, Shapiro et al. (Current Biology, 15 March 1998) and Gaasterland (Nature Biotechnology, July 1998).

This rejection is maintained for reasons of record.

Applicant continues to argue with respect to publication dates. The effective filing date of the instant application is 1/22/99. As such, Shapiro et al. and Gaasterland are prior art by publication date. The remaining references are applied for what they collectively teach was known in the art at the time of the invention.

Again, 35 USC 102(a) is not limited to description in a printed publication before the invention thereof by the applicant for patent. It includes whether the invention was **known** by

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others in this country before the invention thereof by the applicant for a patent. The fact that this meeting (as well as the other meetings cited above and publications discussing the meetings cited above) took place or references were published prior to applicant's filing date indicates that the invention was known. The content of what was discussed at each of these meetings prior to the filing date of the invention has not been rebutted by applicant. In fact, the exhibits presented from inventor Henderson support the examiner's position as set forth in the prior Office action.

Applicant argues with respect to enabling disclosure. It is not clear from the arguments what they are arguing is not enabled.

Applicant continues to argue with respect to the interpretation of the term "system" in claims 1-6. According to Webster's dictionary a system is "a regularly interacting or interdependent group of items forming a unified whole." This is the basis for the examiner's questioning under 112, 1st and 2nd paragraph, as to how the recited components in the system of claims 1-6 are supposed to be linked or integrated, whether the intent was a turn-key system or discrete and independent components. The claims as written do not require that the output from any means must be in a form to act directly, automatically, seamlessly, or otherwise, as input for the next means. As such, each of these discrete components (a database with sequence, structural, and functional information; at least one bioinformatics tool capable of clustering; protein synthesis means with screening means; protein processing means; crystallization means; X-ray crystallography means; structure extraction means able to build a refined model; and a homology building tool) having the functionality required by the claims, would have been discussed at these various meetings and thus the system as claimed (when viewed as discrete pieces of apparatus) would clearly have been known. The embodiment of the system where the

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components are integrated to the degree that the output of one means could be used by another means, for example the protein synthesized by the protein synthesis means used by the crystallization means, would also clearly have been known. The use of multiple known methodologies in combination to solve the structural genomics problem was clearly known at the time of the invention.

Claims 1-12 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter in view of the Workshop on Structural Genomics held at Argonne National Laboratories held January 1998, National Institute of General Medical Sciences (NIGMS) Protein Structure Initiative (PSI) held 4/24/98, NIGMS Genomics Project Planning Meeting held 11/24/98, Structural Genomics Meeting held October 1998 in Avalon, New Jersey, and Gaasterland (Nature Biotechnology, July 1998).

This rejection is maintained for reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa